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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,781	01/09/2001	Roopa Reddy	PC-0032 US	8475

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EXAMINER
RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
1642	11

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/757,781	REDDY ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2002 and 22 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *2 and 9-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☒ Interview Summary (PTO-413) Paper No(s). 11 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The election with traverse filed August 22, 2002 in Paper Nos. 8 and 10 is acknowledged and has been entered. Applicants have elected to prosecute the claims of group II, namely claims 1 and 3-8 insofar as the claims are drawn to a nucleic acid molecule having a polynucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO: 2 or a variation thereof having at least 95% identity to SEQ ID NO: 2, or the complement thereof, a composition comprising said nucleic acid molecule, a vector comprising said nucleic acid molecule, a host cell comprising said vector, and a method for using a cDNA to produce a protein. In addition, after clarifying Applicants' election in a telephone interview with David Streeter, Ph.D. on September 25, 2002, it was determined that Applicants elected the species of invention wherein said cDNA of claim 4 is a fragment of SEQ ID NO: 20 or the complement thereof, and the subspecies of invention wherein said fragment of SEQ ID NO: 20 is SEQ ID NO: 21; see the Interview Summary of September 25, 2002 attached hereto in Paper No. 11.

2. The amendment filed June 26, 2002 in Paper No. 8 is acknowledged and has been entered. Claim 1 has been amended.

3. The amendment filed August 22, 2002 in Paper No. 10 is acknowledged and has been entered. Claims 1, 3, and 4 have been amended.

4. Claims 1-22 are pending in the application. Claims 2 and 9-22 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in Paper Nos. 8 and 10.

5. Claims 1 and 3-8 are currently under prosecution.

Election/Restrictions

6. Applicants' grounds of traversal of the restriction requirement are acknowledged. Applicants have argued that the restriction requirement is improper because the searching more than one of the groups of invention would not constitute a serious burden. Applicants have also argued that the requirement misrepresents the concept of election of species because claims 13 and 17 are drawn to methods of use of the compositions of group I, not to products.

Applicants' arguments have been carefully considered but not found persuasive. The search required for examination of any one group of inventions is not co-extensive with the search required for examination of any other group of inventions; therefore, different searches would be required to examine each different invention. Accordingly, examining more than one group of inventions would constitute a serious burden. Furthermore, claims 13 and 17 are drawn to methods for screening a plurality of molecules or compounds; the plurality of which is defined in dependent claims 14 and 18, respectively. Therefore, claims 13 and 17 are drawn to a plurality of patentably distinct species; and Applicants are referred to section 6, page 9 of Paper No. 9, the Office action mailed June 4, 2002 in which Applicants were notified that traversing on the ground that the species are not patentably distinct requires submission of, or identification of evidence of record that the species are obvious variants. As Applicants have not submitted or identified such evidence, nor clearly admitted on the record that the species are not patentably distinct, the requirement is still deemed proper and is therefore made FINAL.

Specification

7. The disclosure is objected to because the disclosure refers to embedded hyperlinks and/or other forms of browser-executable code, which are impermissible and require deletion. See pages 31 and 33, for examples.

The attempt to incorporate essential or non-essential subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable

code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding incorporation by reference.

Deletion of the references to hyperlinks or other forms of browser-executable code is required in reply to this Office action.

Claim Objections

8. Claims 1 and 3-8 are objected to because of the following informalities:

Claims 1 and 3-8 are objected to because the claims are drawn in the alternative to the subject matter of non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1 and 3-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a cDNA, which the specification defines on page 7. According to the definition provided, the claims encompass a genomic DNA molecule encoding a protein having the amino acid sequence set forth in SEQ ID NO: 2 or a variant thereof having an amino acid sequence that is at least 95% identical to the amino acid sequence of SEQ ID NO: 2. Furthermore, the claims are specifically drawn to a cDNA encoding a naturally occurring variant of the polypeptide of SEQ ID NO: 2.

The specification describes a consensus polynucleotide sequence of a group of putatively overlapping DNA molecules that were synthesized using different messenger RNA molecules or fragments thereof as templates. This consensus polynucleotide sequence is set forth in SEQ ID NO: 20, which the specification teaches encodes the

predicted amino acid sequence set forth in SEQ ID NO: 2. However, the specification does not include a detailed description of a genomic DNA isolate that encodes a protein having the amino acid sequence set forth in SEQ ID NO: 2; nor does it appear that the specification describes any nucleic acid molecule encoding a variant of the polypeptide of SEQ ID NO: 2 having an amino acid sequence that is at least 95% identical to SEQ ID NO: 2.

The content of the specification is not reasonably commensurate in breadth with the claims, as the specification fails to amply describe at least a substantial number of nucleic acid molecules that are encompassed by the claims to reasonably convey to the skilled artisan that the Applicants had possession of the claimed invention at the time the application was filed. Moreover, while on page 9 the specification defines "variant" as "recognized variants of a cDNA", it is noted that the specification fails to describe features that are common to at least a substantial number of members of the claimed genus of cDNA molecules; therefore, the skilled artisan could not immediately envision, or recognize at least a substantial number of the members of the claimed genus. Additionally, the skilled artisan could not distinguish members of the claimed genus from other cDNA molecules, which are not regarded as part of the invention, as it appears the specification provides no means of doing so.

11. Claims 1 and 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 4 recite the terms "a naturally occurring variant of [...] SEQ ID NO:2" and "a naturally occurring variant of [...] SEQ ID NO:20", respectively. However, there does not appear to be proper and sufficient antecedent basis in the specification for recitation of these terms in the claims. Therefore, recitation of the terms in the claims appears to introduce new matter and thereby violates the written description requirement set under 35 USC § 112, first paragraph.

If Applicants were to point to specific disclosures in the specification that are believed to provide the necessary support for these terms, these matters might be resolved.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1 and 3-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1, 3, and 5-8 are vague and indefinite because claims 1 and 3 recite the term "isolated cDNA [...] encoding a protein". Recitation of the term renders the claims vague and indefinite because on page 7 the specification defines the term "a cDNA encoding a protein" as "a nucleic acid sequence that closely aligns with sequences which encode conserved regions, motifs or domains that were identified by employing analyses well known in the art". Therefore, it is unclear how closely the claim requires the claimed nucleic acid sequence to align with sequences that encode conserved regions, motifs, or domains of a protein having the amino acid sequence set forth in SEQ ID NO: 2 or a naturally occurring variant thereof. Additionally, it is unclear to which conserved regions, motifs, or domains of the amino acid sequence of SEQ ID NO: 2, an antigenic epitope thereof, a biologically active portion thereof, or variant of SEQ ID NO: 2 the claims require the claimed nucleic acid sequence to closely align. Finally, it is unclear which analyses, which are well known in the art, were used to identify said conserved regions, motifs, or domains. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

(b) Claim 3 is vague and indefinite because the claim recites the term "biologically active portion of SEQ ID NO:2". Recitation of the term renders the claim vague and indefinite because any and all biological materials, e.g., a carboxyl group, which is indeed a portion of material represented by SEQ ID NO: 2, are biologically active in many regards; thus, the claim is so broad as to be vague and indefinite.

Accordingly, it cannot be ascertained how recitation the term is meant to limit, or delineate the subject matter that Applicants regard as the invention and therefore one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

(c) Claim 4 is indefinite because it is unclear whether the claim requires the cDNA to consist of or comprise a nucleic acid sequence of SEQ ID NO: 20 or the complement thereof, to consist of or comprise a fragment of SEQ ID NO: 20 selected from the group consisting of SEQ ID NOs: 21-39 or the complements thereof, or to comprise or consist of a naturally occurring variant of SEQ ID NO: 20. Accordingly, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

(d) Claim 8 is indefinite because the claim recites "using a cDNA to produce a protein". The claim does not clearly delineate the metes and bounds of the invention, as it cannot be determined whether the protein to which the phrase refers is the protein encoded by the cDNA molecule of claim 1 or any cDNA molecule of which the cell is comprised.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

15. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

16. Claims 3 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Joberty, et al (*Nature Cell Biology* **2**: 531-539, 2000).

Joberty, et al teach a nucleic acid molecule having a polynucleotide sequence that encodes a protein having an amino acid sequence that is deemed the same as an antigenic epitope of SEQ ID NO: 2 or a biologically active portion of SEQ ID NO: 2, absent a showing of any differences. The Office, however, does not have the facilities for examining and comparing Applicants' product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural, and functional characteristics as the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed product is different than that taught by the prior art. Furthermore, the nucleic acid molecule of the prior art comprises a nucleic acid sequence of SEQ ID NO: 20.

17. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Izumi, et al (*Journal of Cell Biology* **143**: 95-106, 1998).

Izumi, et al teach a nucleic acid molecule having a polynucleotide sequence that encodes a protein having an amino acid sequence that is deemed the same as an antigenic epitope of SEQ ID NO: 2 or a biologically active portion of SEQ ID NO: 2, absent a showing of any differences. Furthermore, the nucleic acid molecule of the prior art comprises a nucleic acid sequence of SEQ ID NO: 20.

18. Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by NCI-CGAP (Database GenBank Accession No. AI079538, 1998).

NCI-CGAP teaches the polynucleotide sequence of nucleic acid molecule that encodes a protein having an amino acid sequence that is deemed the same as an antigenic epitope of SEQ ID NO: 2 or a biologically active portion of SEQ ID NO: 2, absent a showing of any differences. The nucleic acid molecule of the prior art comprises a nucleic acid sequence of SEQ ID NO: 20; in fact, the nucleic acid molecule comprises SEQ ID NO: 21.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
November 26, 2002

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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